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09/423,037

02/22/2000

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08/09/2006

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EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/423,037 | HEERY ET AL. | |
| | Examiner | Art Unit | |
| | Jennifer Dunston | 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-22 is/are pending in the application.
- 4a) Of the above claim(s) 5,6 and 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 7-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/22/2005 has been entered.

Receipt is acknowledged of an amendment, filed 12/22/2005, in which claims 2 and 23 were canceled; and claims 1, 3, 5, 7, 8, 9, 12-14 and 19 were amended. Currently, claims 1 and 3-22 are pending.

Any rejection of record in the previous office actions not addressed herein is withdrawn. New grounds of rejection are presented herein that were necessitated by applicant's amendment of the claims since the office action mailed 6/20/2005.

Election/Restrictions

Applicant elected Group I, LXXLL, SRC-1 and oestrogen receptor species without traverse in the reply filed 11/13/2001.

Claims 14-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 11/13/2001.

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Claims 5-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/2001.

Currently, claims 1, 3, 4 and 7-13 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4 and 7-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The introduction of the limitation of “only one signature motif B¹XXLL” into the claims resulted in the introduction of new matter. This limitation is not described in the present specification as filed. The specification describes a yeast two-hybrid assay where only one LXXLL motif is used to map the nuclear receptor interaction domains within SRC-1 (e.g. page 14). The results of this assay demonstrate that the LXXLL motif is sufficient to bind nuclear receptors. The specification does not describe the use of a fragment of a nuclear protein that contains only one B¹XXLL (or only one LXXLL) motif in the context of the claimed assay to

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identify inhibitor compounds capable of reducing the interaction between the protein fragment containing the B¹XXLL motif and a liganded nuclear hormone receptor.

The response notes that the limitation of canceled claim 23 has been introduced into claim 1. Claim 23 was newly added in the reply filed 3/28/2005. The reply filed on 12/23/2002 asserts, "Support of the subject matter of this new claim is found throughout the application." The reply filed 12/22/2005 asserts that support is found in the working examples of the specification at pages 14-24. However, the examples presented on page 14-24 are not working examples of the claimed invention of claim 1. At page 18, lines 4-10, the specification discloses that TIF 1 contains a single LXXLL motif and TRIPs2-5, TRIP8 and TRIP9 contain at least one copy of the LXXLL motif. Example 6 teaches an *in vitro* binding assay that includes SRC1 protein; however, it appears as though more than one LXXLL motif, or mutant form thereof, was included in the SRC1 proteins. Even if only one motif was included in the SRC1 proteins of Example 6, this would only provide support for the specific embodiment of the claimed assay disclosed in Example 6 and would not provide support for the genus of methods currently claimed.

Accordingly, the amendment is a departure from the specification and claims as originally filed, and the passages that Applicant has provided do not provide support.

Response to Arguments

The previous rejection of claims 1, 3-4, 7-13 and 23 under 35 USC 112, first paragraph, has been withdrawn in view of Applicant's amendment to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7, 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (Nature, Vol. 374, pages 91-94, 1995; see the entire reference) in view of Onate et al (Science, Vol. 270, No. 5240, pages 1354-1357, 1995; see the entire reference).

Lee et al teach that Trip1 interacts with thyroid hormone receptor *in vivo* when the hormone receptor is bound to T₃ ligand (e.g. paragraph bridging pages 91-92; paragraph bridging pages 93-94). The sequence presented at page 93, Figure 2a, indicates that only one B¹XXLL motif is present within the protein (MXXLL, amino acids 273-277). Lee et al teach placing the fragment of Trip 1 comprising the MXXLL motif in contact with the liganded nuclear thyroid hormone receptor transcription factor and detecting the presence of an interaction in the context of a yeast two-hybrid assay (e.g. paragraph bridging pages 91-92). Lee et al suggest that further

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analysis of the interaction between Trip1 and thyroid receptor will be required to define the nature of these interactions precisely.

Lee et al do not teach further contacting Trip1 and the liganded thyroid hormone receptor with a potential inhibitor compound.

Onate et al teach the interaction of SRC-1 with liganded progesterone receptor in a yeast two-hybrid assay (e.g. page 1354, left column). Onate et al teach the addition of an NH₂-truncated form of SRC-1 to the interaction of the progesterone receptor and SRC-1 to determine whether it would have an effect on the interaction (e.g. page 1356, left column). Onate et al teach that the ability of the truncated SRC-1 to act as a dominant-negative repressor suggests that it is a genuine coactivator for steroid receptor target gene expression (e.g. page 1356, left column).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of interacting the Trip1 and liganded thyroid receptor of Lee et al to include the use of a truncated form of Trip1 as a potential dominant negative inhibitor of the interaction in the yeast two hybrid assay of Lee et al, as taught by Onate et al for the interaction of SRC-1 and liganded progesterone receptor, because Lee et al and Onate et al teach it is within the ordinary skill in the art to use yeast two hybrid systems to study the interaction of liganded hormone receptors and their protein cofactors.

One would have been motivated to make such a modification in order to receive the expected benefit of being able to better understand the interaction of Trip1 and thyroid receptor as suggested by Lee et al and to determine whether Trip1 is a genuine coactivator for thyroid receptor as taught by Onate et al. Based upon the teachings of the cited references, the high skill

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of one of ordinary skill in the art, and absent any evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

jad

CELINE QIAN, PH.D.
PRIMARY EXAMINER

